U.S. Antitrust Modernization Commission

"Antitrust and the New Economy"
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I am Senior Vice President and General Counsel of Cephalon, Inc., a leading biopharmaceutical company based in suburban Philadelphia and dedicated to the discovery, development and marketing of innovative products to treat sleep and neurological disorders, cancer and pain. Cephalon currently employs approximately 2,500 people in the United States and Europe, has sales revenue of just over one billion dollars, and markets four proprietary products in the United States: PROVIGIL® (modafinil) Tablets [C-IV], GABITRIL® (tiagabine hydrochloride), ACTIQ® (oral transmucosal fentanyl citrate) [C-II] and TRISENOX® (arsenic trioxide) injection, as well as more than 20 products overseas.

Prior to joining Cephalon in 1997, I worked for several years at The DuPont Merck Pharmaceutical Company, last as Vice President and Associate General Counsel. Prior to that, I served in the George H.W. Bush administration with the U.S. Department of State, practiced corporate law and clerked for a U.S. Court of Appeals judge. I also hold a visiting appointment in politics at Princeton University, serve on the board of governors of the East-West Center in Honolulu, and have been elected to membership in the American Law Institute and the Council on Foreign Relations.

I am very pleased to have the opportunity to appear before the Commission today to provide some thoughts on the application of antitrust law to the life sciences, one of the most significant of the several technology-based industries that comprise the so-called "New Economy." Although I hold a law degree, I am not an antitrust law specialist. Rather, I have been asked to

provide views in my capacity as a senior executive with a biopharmaceutical company so as to provide a business perspective on this important topic.

I. Summary

Although I will offer some broad observations related to the application of antitrust law to pharmaceutical and biotechnology industry transactions, my immediate experience in this area came from an extensive Hart-Scott-Rodino antitrust clearance review by the Federal Trade Commission (FTC) during 2003 and 2004 of the proposed acquisition by Cephalon of CIMA LABS INC. With this in mind, I want to make clear that it is not my purpose in appearing to reargue the issues that arose in this review, nor to complain about the manner in which the FTC conducted its work. I only wish to raise questions that reflect my experience so that the Commission might consider the wisdom of our current policies and practices in this area.

Among the questions posed by this Commission is, "What features, if any, of dynamic, innovation-driven industries pose distinctive problems for antitrust analysis...?" Based on my experience, I would make three observations as to the pharmaceutical and biotechnology industries. First, it seems to me that there are several aspects inherent in the life sciences business that make traditional antitrust analysis challenging. To the extent that this traditional analysis is predicated upon economic models that are themselves based upon principles of supply and demand in a free market economy, it is important to take note of several features that are entirely lawful, but which necessarily modify the application of pure free market principles. Specifically, the granting of patents which ensure market exclusivity for a specified period of time, the review and approval of marketing applications by a regulatory agency that establish a barrier to entry

by third parties, and the presence of consumer, prescriber and payor as separate decision makers or influencers, may all have the effect of limiting the utility of traditional economic models.

Second, it is very important to appreciate that mergers and acquisitions in the pharmaceutical industry are an integral part of the innovation process itself. In some cases, the consumer benefits that are derived from the introduction and broad commercialization of a new product will come only if a smaller firm and its innovative compound or product is acquired by a larger firm. Indeed, many early stage inventions are pioneered at small, entrepreneurial companies that are steeped in scientific talent but lack the clinical, medical, financial, managerial, organizational, regulatory, and legal resources required to take a product from that early stage through development, clinical testing, regulatory approval and commercial marketing.

Third, in defining the relevant product market and identifying competitive effects in a complicated, technology-based industry, the antitrust agencies need to be thoroughly educated and sophisticated in their analysis. I recognize that this is no small task. Organizational behavior theory suggests government agencies are more successful over time if they have a narrow, clearly defined mission that all employees share. From my observation, the FTC believes that it has such a mission: with respect to the group charged with merger analysis, the FTC is singularly focused on ensuring that it block any merger that *MIGHT* turn out to be anticompetitive. To prevent this from occurring, the FTC staff, time and time again, creates highly imaginative "what-if" scenarios that defy conventional wisdom, practice, and experience in the pharmaceutical industry. Rather than dealing with what was likely to happen, their review in the Cephalon/CIMA matter

focused on what was theoretically possible, consistently interpreted facts against the prospective acquirer, and placed upon Cephalon the obligation of proving that their imagined scenarios would not occur. I would submit that this anti-merger bias, though perhaps consistent with the burden placed on firms in connection with the HSR review process, is antithetical to the potential consumer benefits of many acquisitions in the life sciences.

This approach was crystallized for us when we were told by a Commission staffer, "the Commission does not do risk." In this context, what does that mean? Clearly, the FTC was engaged in an inherently uncertain, predictive exercise. As Yogi Berra has famously said, "It's tough to make predictions, especially about the future." If the Commission were trying in an even-handed manner to balance the risks and uncertainties on both sides, a statement that "the Commission does not do risk" would be nonsensical. It would be tantamount to saying, "we refuse to evaluate this merger at all, because we are unwilling to deal with uncertainties." But, of course, that was not what the FTC staffer intended. Rather, I believe that the Commission discounts to zero any risk of harm from erroneously blocking a procompetitive merger, and weighs only the risk, however minuscule, of failing to block an anticompetitive one. Given the importance of mergers and similar transactions in bringing innovation to fruition in this industry, that is not an acceptable approach.

II. Characteristics of the Pharmaceutical Industry That May Affect Competition Analysis

A. The Nature of Risk in the Pharmaceutical Industry

Uncertainty is the most fundamental characteristic of new drug development in the pharmaceutical industry. The principal source of that uncertainty is that the effects, positive and negative, of a new drug are not fully known if ever until firms conduct extensive clinical testing. The testing begins with so-called Phase I testing on a small number of healthy volunteers, principally to establish safe dosages; proceeds to Phase II testing on subjects with the disease to obtain further evidence on safety and preliminary data on efficacy; and finally concludes with Phase III trials on large numbers of subjects to more clearly demonstrate effectiveness as well as safety. A proposed new drug can fail at any of these stages for any number of reasons. Even when clinical trials appear to be successful, the FDA can determine not to approve a product candidate or, if the drug is already approved, the FDA can force a withdrawal of the product following approval if serious adverse effects occur post-marketing. According to an FTC report, for every 5,000-10,000 compounds screened in preclinical testing, only five reach the clinical testing phase, and only one receives FDA approval.[1] Many of the failures come extremely late in the process, after considerable investment of time and significant financial

[1] Roy Levy, THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE, Federal Trade Commission Bureau of Economics Staff Report 178 (March 1999), *available at* http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf.

resources has been made. Recent estimates suggest that the average new drug takes an average of 12 to 15 years to discover[2] at a cost of approximately $800 million.

B. Patents

Intellectual property lies at the heart of the life sciences industry. Patents are granted to inventors for a period of 20 years following the date of filing with the U.S. Patent and Trademark Office, though much of this time is consumed by the requisite FDA review period prior to the commercial launch of a product (as recognized under the accommodations established in the Hatch-Waxman Act). Although patents, especially those covering the active ingredient in a drug, are effectively lawful monopoly grants for a limited period of time, they are critically important to ensure a thriving life sciences industry that will continue to discover and develop innovative medicines; this is self-evident in consideration of the aforementioned costs and risks associated with this process.

C. Regulatory Constraints

As noted above, risk in the pharmaceutical industry derives not only from the uncertainty as to the effects of a new drug, but also from regulatory risk. Pharmaceutical and biotechnology companies are not free to act on their own, but rather are subject to the scrutiny of regulatory agencies that oversee the development and marketing of their products.

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2 J.A. DiMasi, R.W. Hansen, and H.G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECONS. 151 (2003).

(i) FDA

The FDA regulates the research, development, and marketing of pharmaceuticals. Under the Federal Food, Drug and Cosmetic Act, any person seeking to market a new drug, must first obtain FDA approval by filing a NDA establishing the drug is safe and effective for its intended use. The Hatch-Waxman Act established a streamlined approval process for generic versions of approved drugs with the same active ingredients by authorizing Abbreviated New Drug Applications (ANDAs) for generic drugs that are bio-equivalent to pioneer drugs, as well as paper new drug applications (paper NDAs) that rely on published literature to demonstrate safety and efficacy.

(ii) Drug Enforcement Administration (DEA)

Some pharmaceutical products contain controlled substances. The Controlled Substances Act (CSA), which is administered by the DEA, mandates that the DEA prevent, detect, and investigate the diversion of legally manufactured controlled substances while, at the same time, ensuring that there are adequate supplies to meet the legitimate medical needs in the United States. In addition, the DEA controls schedule I and II substances at the manufacturing level with quotas, and monitors their distribution to pharmacy wholesalers. Certain states also maintain prescription monitoring programs, which the DEA helps administer and can access to observe distribution trends and to investigate questionable prescribing practices.

D. Customers

Several different groups of market participants are involved in decisions to use pharmaceuticals, which may complicate market definition analyses. Although the patient actually consumes the product, patients cannot obtain prescription pharmaceuticals without a physician's prescription, and physicians have broad discretion to prescribe alternative products. Indeed, pharmaceutical companies expend substantial sums on physician-directed marketing efforts, including so-called "detailing" visits by sales representatives, free samples, advertising in scientific and medical journals, and sponsorship of continuing medical education programs.

Third party payors also play a critical role in the competitive dynamics of pharmaceutical markets, particularly with respect to generic products. As of the end of last year, thirty-nine states had enacted mandatory generic substitution laws requiring that the generic version of a drug be dispensed to Medicaid beneficiaries when available. Furthermore, many managed care organizations provide financial incentives to pharmacies and patients to induce them to dispense or use generic products rather than branded ones, including the use of multi-tiered formularies with different co-payment levels for different types of drugs. Many managed care organizations also use prior authorization requirements that make it harder to use proprietary drugs when generic alternatives are available. Quite often, such organizations also pay pharmacists higher dispensing fees for favored drugs, limit reimbursement levels where lower-cost alternatives are available, and pay

pharmacists incentives for achieving levels of performance in distributing favored drugs.

E. Mergers and Acquisitions As a Tool of Innovation

Merger and acquisition activity in the pharmaceutical industry is a critical part of drug development. Small, specialized firms account for much of the innovation of novel pharmaceutical and biotechnology products. Typically, these firms include able teams of scientists that are focused on discovering new drugs. Once a compound is discovered, however, these firms often lack the resources and expertise to design and execute clinical studies, navigate the FDA regulatory process, and commercialize the product. Thus, but for investment from larger drug and biotech companies, smaller R&D firms would not be able to further develop their novel compounds.

Cephalon's acquisition of Anesta Corp. in 2000 is a good example of how acquisitions can foster innovation and benefit consumers. When Cephalon acquired Anesta, ACTIQ was an approved but fledgling product with modest sales; with Cephalon's regulatory and marketing expertise, the firm was able to better communicate the benefits of ACTIQ to many more physicians. This greatly benefited their patients, whose pain could now be managed in a superior way. The development and commercialization of new drugs, therefore, often requires larger pharmaceutical companies to ally with the smaller research stage firms; to unnecessarily block the consummation of such deals could very well dampen the innovative spirit of this industry.

III. The Cephalon/CIMA Merger Transaction

A. Products

(i) ACTIQ

ACTIQ is an opioid pain reliever containing the active ingredient fentanyl, a well known agent whose patents have long since expired. There are literally dozens of fentanyl-based products approved by FDA for the management of pain. ACTIQ uses a unique and patented system for rapid delivery of fentanyl into the bloodstream: the medication is in the form of a compressed powder lozenge mounted on a stick-like handle, and the ACTIQ unit is placed between the cheek and gum and twirled as the patient sucks on the unit. As the lozenge dissolves, a portion of the medication is absorbed quickly across the lining of the mouth ("transmucosally") into the bloodstream. As soon as the drug enters the bloodstream, it is carried throughout the body, including the central nervous system, where it begins to relieve pain.

FDA concerns that the ACTIQ handle made the product look like a "lollipop" resulted in approval of an extremely narrow product label, namely for the management of so-called breakthrough pain ("BTP") in cancer patients with malignancies who are already receiving, and who are tolerant to, opioid therapy for their underlying persistent cancer pain. In fact, there is no valid medical distinction of which I am aware that distinguishes between pain caused by cancer, and pain caused by any other medical condition. Within that narrow product niche, however, the ACTIQ handle was also a compelling factor for some patients, because it offered a considerable degree of control

over the amount of product was actually used for a given episode of pain ("self-titration") and because the perception of control may itself have some therapeutic benefits.

(ii) Oravescent Fentanyl

OraVescent Fentanyl (OVF) is a rapidly dissolving buccal tablet (that is, a tablet held in the cheek and absorbed across the mucosal membranes lining the mouth). It does not incorporate a handle into its design. It achieves transmucosal absorption using CIMA's OraVescent technology, an effervescent technology that both ensures rapid dissolution and improves the absorption of active drug ingredients across the mucosal membranes. Because the product does not have a handle and because of its rapid dissolution, it lacks the "self-titration" feature of ACTIQ, but it also has a degree of convenience that makes it appealing for a wider range of patients for whom the need to twirl and suck is a disadvantage. If OVF is to be approved, Cephalon's management believes that the two products will be highly differentiated, in a market in which there are many existing fentanyl-based products as well as many new delivery systems under development.

At the time of the acquisition, CIMA was just beginning Phase III studies for OVF. FDA approval was years away. Since completing the acquisition last year, Cephalon completed the Phase III clinical studies, and it filed a New Drug Application (NDA) for OVF with the FDA on September 30, 2005. At the time of the transaction, the regulatory path of OVF was, and it remains,

uncertain, although Cephalon estimates that the FDA could approve the drug by late 2006.

Moreover, if Cephalon had not acquired CIMA, but instead CIMA had partnered with a third party, there is no reason to believe that the other partner would have positioned OVF to be a competitor to ACTIQ. ACTIQ was nearing the end of its patent life, and a generic alternative to ACTIQ was clearly likely to be introduced. The FTC staff responded to this prospect insisting that such a generic MIGHT not yet be approved at the time OVF would have been approved in the hands of CIMA or another partner. In the staff's view, that could mean that the acquisition by Cephalon would eliminate a few months of head-to-head competition between ACTIQ and OVF. Despite our many discussions to this effect, they would not accept that CIMA or another partner would not likely position OVF to compete with ACTIQ in any event, regardless of whether or not a generic version of ACTIQ was yet approved, as long as approval of a generic version of ACTIQ was expected in the near term. This is because, if OVF were positioned as a "me-too" product rather than as a new innovation product innately superior to all existing fentanyl-based offerings, generic ACTIQ entry would destroy OVF's market as soon as it entered, given the third-party payor environment in which pharmaceutical companies now operate.

B. Federal Trade Commission Review and the Consideration of Risk

Analyzing the competitive effect of a proposed transaction obviously is a prospective exercise; the principal goal of merger analysis is to predict how the

combination of two firms will affect competition. Thus, how the antitrust agencies address the uncertainty of the effects of a proposed merger is a critical part to the review process. Unfortunately, my experience with the Cephalon/ CIMA matter suggests that the FTC does not yet have the sophisticated approach to uncertainty that it needs to deal properly with industries operating in the "New Economy". I hope that our discussion here today will make some small contribution to the development of that approach.

In the Cephalon/ CIMA matter, there were a number of factors influencing the analysis that were uncertain: if and when generic ACTIQ would enter the market, if and when alternative proprietary products would be approved, and when the FDA would approve OVF, if at all. Rather than deal with risk symmetrically, the FTC resolved every uncertainty against the merger.

(i) Generic Entry

ACTIQ began to achieve commercial success only near the end of its patent life, and sales levels suggested that the product would likely attract five or more generic copies.[3] There are numerous generic companies that are licensed to manufacture and do sell pharmaceuticals containing one or more of the following opioids: morphine, oxycodone, hydro-morphone, hydrocodone, codeine, and fentanyl. Cephalon was aware that at least three generic pharmaceutical companies had demonstrated an interest in developing a generic ACTIQ product. Indeed, shortly after the conclusion of the FTC's

3 The Bureau of Economics estimates that where revenues of a branded product are approximately $95 million per year before patent expiry (well below ACTIQ's current performance), the likelihood that five or more generic products are approved is approximately 89%. *See Generic Drug Industry Dynamics* (Feb. 2002 general).

investigation, Barr filed an ANDA seeking approval to market generic ACTIQ.

The FTC concluded, however, that generic entry *might* not occur, or might not occur soon enough, for a variety of reasons that seemed to me highly speculative. For example, the FTC expressed great concern that the filing of a meritless Citizen Petition could delay the entry of a generic version of ACTIQ for a considerable period of time□a prospect that is remote at best given the increasing sophistication of the FDA in routinely dismissing Citizen Petitions. Similarly, the FTC staff expressed concern that making a product with a lollipop-like stick could be so difficult that the generic companies might be delayed in being able to manufacture the product. This fear was expressed despite evidence that Cephalon's subsidiary, Anesta Corp. (a company that had no manufacturing experience before making ACTIQ) used standard industry equipment to make the product, with the stick-like handle being glued into a compressed-powder lozenge made with traditional pill-making equipment. In the end, the FTC apparently was simply unwilling to accept a minuscule risk that sophisticated, well funded companies specialized in manufacturing pharmaceuticals could not make ACTIQ or would be delayed unreasonably in doing so.

(ii) Proprietary Entry

The FTC's aversion to any risk of possible anticompetitive effects was particularly evident in its proprietary entry analysis. The untapped opportunity for breakthrough pain treatments has attracted over a dozen

companies developing proprietary short-acting opioid products. Many companies are applying their drug delivery technologies to speed fentanyl and other opioid absorption, whether inhaled, intranasal, sublingual, or transdermal. For example, during the FTC's investigation, Johnson & Johnson (J & J) filed an NDA for its E-Trans fentanyl product, a battery-powered patch that allows for on-demand delivery of fentanyl with rapid absorption. J & J already marketed a successful long-acting pain drug delivered through a Duragesic patch; thus, E-Trans would be marketed as part of a pain franchise by a large and sophisticated sales team.[4] In summary, it seemed highly likely that there would be other proprietary drugs treating severe pain before, at the same time as, or shortly following, the date of OVF approval.

The FTC, however, declined to consider any of the products under development by these companies as potential competitors with either ACTIQ or OVF. The agency dismissed some products because they had different delivery methods or different mechanisms of action. It dismissed others because they relied on a different active ingredient. The FTC dismissed still other potential entrants because it did not believe the companies were well funded. The FTC worried that some doctors may not be comfortable with certain products. The FTC also rejected some entrants because the product was too deemed to be early in its development.

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[4] Other examples include Nastech, which is developing an intranasal morphine product; Orexo Pharmaceuticals, which is developing a fentanyl sublingual tablet, Rapinyl; and Aradigm Corporation, which has completed Phase IIb studies for an inhaled morphine product.

(iii) OVF Approval Prospects

However, when it came time to consider the likely approval timeframe and market potential of OVF, the FTC did not view the situation through the same risk-averse lens, even though there were significant risks associated with the product. OVF uses the novel OraVescent drug delivery technology; the FDA has never before considered or approved a drug with that technology. Just as the regulatory paths of other potential entrants are fraught with uncertainty, so there is uncertainty surrounding FDA approval of OVF, its timing, and the restrictions that could accompany such approval. CIMA, a company that had never before taken a drug through the FDA regulatory process, had estimated OVF approval in late 2005. The FTC cited this wildly optimistic estimate, and declined to accept our more realistic assessment. In the end, the CIMA timeline proved unrealistic, and Cephalon currently estimates OVF approval in late 2006.

Thus, the FTC demonstrated an inconsistent application of risk calculus in their analysis. For purposes of evaluating possible market entry, the FTC weighed all risks against those other products in development; however, for purposes of determining whether there might, absent the merger, be competition between ACTIQ and OVF, the FTC heavily discounted any commensurate risks surrounding OVF approval. That inconsistent treatment is even more unbalanced than it sounds, because of the sheer number of

products in development, any one of which would more than make up for any loss of competition between ACTIQ and OVF.

IV. Product Market Definition/ Competition Between OVF and ACTIQ

In merger investigations, the determination of the relevant product is often the most critical issue, and that is certainly true for pharmaceutical and biotechnology transactions. However, despite the FTC having challenged several dozen mergers involving pharmaceutical companies in the past 20 years, the agency's approach to product market definition is still less than transparent.

The FTC has defined markets in the following ways:

- whether drugs treat the same disease, condition, or indication (See Pfizer/ Pharmacia – research and development, and manufacture and sale of prescription drugs for the treatment of erectile dysfunction; SmithKline/ Glaxo – drugs for the treatment of irritable bowel syndrome)
- whether the drugs have the same mechanism of action (See Amgen/ Immunex – separate product markets for drugs that treat rheumatoid arthritis with (1) TNF inhibitors and (2) IL-1 inhibitors; Upjohn/ Pharmacia – research, development, manufacture and sale of topoisomerase I inhibitors for the treatment of colorectal cancer)
- whether the drugs have the same specific chemical compound (See SmithKline/ Glaxo – drugs that contain ceftazidime; Baxter/ Weyth – manufacture and sale of Propofol)
- whether the drugs have the same delivery method (Glaxo/ Burroughs Wellcome – oral drugs to treat migraines)
- whether the drugs have the same frequency of dosage (Pfizer/ Pharmacia – extended release drugs for treatment of overactive bladder; Hoechst/ Marion Merill Dow – once-a-day diltiazem)
- whether the drugs are branded or generic.

In the Cephalon/ CIMA matter, the FTC defined a product market of Breakthrough Cancer Pain drugs, which help to reduce or eliminate the spikes of severe pain that chronic cancer patients experience. The FTC also noted that BTCP drugs provide a faster onset of pain relief than other treatments and can be self-administered in convenient and portable dosages, which is important because many BTCP patients are not in hospitals. ACTIQ was the only drug indicated for BTCP, and OVF was the only product in development with that indication the FTC recognized.

As suggested above, this artificially narrow indication was only one feature of the ACTIQ product. The FTC seemed to ignore other distinguishing factors such as the delivery method (stick versus effervescent pill), despite the fact that doctors perceived the stick to be a an important characteristic of ACTIQ. Unlike ACTIQ, but like almost all of the potential proprietary entrants, OVF uses a passive delivery technology: no further action by the patient is required after the lozenge is placed in his or her mouth. It also achieves a concentration level of the active ingredient in the bloodstream similar to ACTIQ in less time and with less total dosage of fentanyl, a powerful narcotic with potential side effects. OVF offers no ability to control titration.

Any competition between the two drugs will only occur if and when the FDA approves OVF, and the nature of that competition will depend not only on the respective product attributes of the two drugs, but also on the other market conditions at the time of OVF approval. Indeed, the product attributes of the two drugs, as perceived by physicians, patients, and managed care, will themselves depend upon promotional efforts that will be shaped by market conditions. The competitive interaction thus depends on a complex interplay among at least the following:

- whether and when FDA approves OVF;
- whether and when entry of a generic form of ACTIQ has occurred or is threatened;
- whether and when entry of other proprietary products targeted at breakthrough pain or breakthrough cancer pain has occurred or is threatened; and
- the perceived product attributes of the two products in light of the actuality or possibility of generic or proprietary entry.

In appearing to ignore or at least substantially discount these many layers of uncertainty, the FTC resolved all unknowns against Cephalon by concluding that OVF was the only likely potential competitor to ACTIQ. Put another way, the Commission concluded that the relevant product market was sufficiently large to include ACTIQ and OVF (after all, in simple terms, they both went into your mouth and contained fentanyl), but sufficiently narrow to exclude all other existing or potential products to treat breakthrough or severe pain.

V. Conclusion

There are substantial costs associated with this kind of review that extend well beyond the payment of fees to lawyers and economists. If the FTC continues to regard pharmaceutical and biotechnology mergers with skepticism, and if they continue to define product markets unduly narrowly, larger firms will begin to shy away from what would otherwise be logical acquisitions of smaller firms that have promising products or nearly-approved products in a therapeutic area in which the larger firm can leverage its existing capabilities to develop and market promising new medicines.

It is enormously important that the antitrust agencies properly consider these issues because, as a practical matter, there is often no recourse to the courts. After more than nine months of FTC review, Cephalon was forced to either accept the FTC's remedy or

abandon its efforts to acquire CIMA. I learned first-hand the tremendous leverage held by the FTC in transactions such as this. The terms of most acquisition agreements require reasonably prompt antitrust clearance, and due to the extent of their review process, the FTC had effectively eliminated our options.

Altering the legal standard of this review would not likely accomplish much. The courts have already prescribed strict standards for potential competition mergers, and I am informed that the FTC, in its last formal opinion on the subject of potential competition, set out a requirement of "clear proof" that the potential competitor would have entered the market and would have exerted a significant competitive effect on the market absent the merger. Since the FTC staff's leverage over a transaction comes from the process itself, the legal standard is largely irrelevant. Instead, absent a significant legislative overhaul of the merger review process, progress in this area depends principally on increased sophistication within the agencies themselves in dealing with issues of technology, uncertainty and risk.